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(71) Applicant: HEARTPORT, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US).

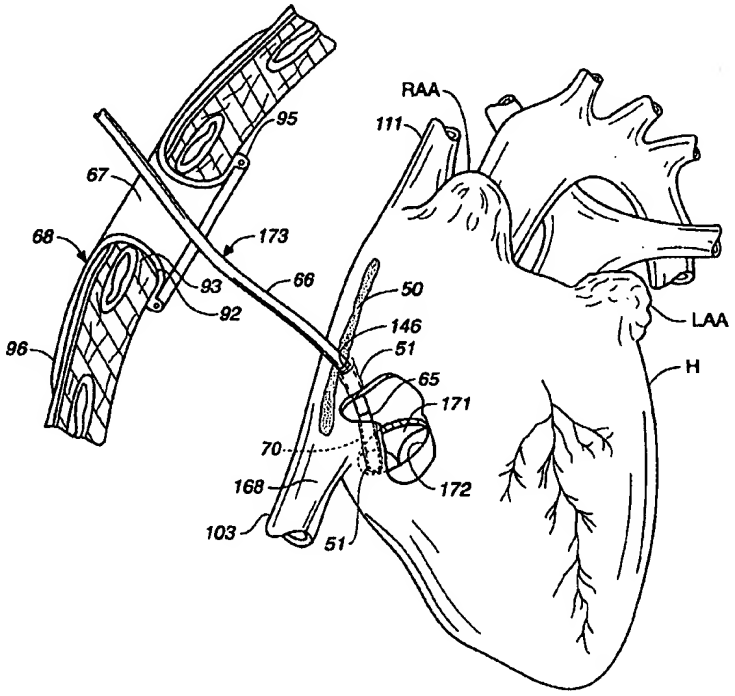
(72) Inventors: COX, James, L.; 7 Dromera Road, St. Louis, MO 63124 (US). BOYD, Stephen, W.; 333 Palomar Drive, Redwood City, CA 94062 (US). GIFFORD, Hanson, S., III; 3180 Woodside Road, Woodside, CA 94062 (US). VASKA, Matthias; 13944 Fremont Pines Lane, Los Altos, CA 94002 (US). MERRICK, Daniel, D.; 168 La Sonoma Way, Alamo, CA 94507 (US).

(74) Agent: HESLIN, James, M.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111-3834 (US).

(54) Title: SURGICAL SYSTEM AND PROCEDURE FOR TREATMENT OF MEDICALLY REFRACTORY ATRIAL FIBRILLATION

(57) Abstract

The invention provides surgical systems and methods for ablating heart tissue within the interior and/or exterior of the heart. A plurality of probes (57) is provided with each probe configured for introduction into the chest for engaging the heart. Each probe includes an elongated shaft (66) having an elongated ablating surface (65) of a predetermined shape. The elongated shaft (66) and the elongated ablating surface (65) of each probe (57) are configured to ablate a portion of the heart. A sealing device (145) affixed to the heart tissue forms a hemostatic seal between the probe and the penetration in the heart to inhibit blood loss therethrough.



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SURGICAL SYSTEM AND PROCEDURE FOR TREATMENT OF MEDICALLY REFRACTORY ATRIAL FIBRILLATION

BACKGROUND OF THE INVENTION

It is well documented that atrial fibrillation, either alone or as a consequence of other cardiac disease, continues to persist as the most common cardiac arrhythmia. According to recent estimates, more than one million people in the U.S. suffer from this common arrhythmia, roughly 0.15% to 1.0% of the population. Moreover, the prevalence of this cardiac disease increases with age, affecting nearly 8% to 17% of those over 60 years of age.

Although atrial fibrillation may occur alone, this arrhythmia often associates with numerous cardiovascular conditions, including congestive heart failure, hypertensive cardiovascular disease, myocardial infarcation, rheumatic heart disease and stroke. Regardless, three separate detrimental sequelae result: (1) a change in the ventricular response, including the onset of an irregular ventricular rhythm and an increase in ventricular rate; (2) detrimental hemodynamic consequences resulting from loss of atroventricular synchrony, decreased ventricular filling time, and possible atrioventricular valve regurgitation; and (3) an increased likelihood of sustaining a thromboembolic event because of loss of effective contraction and atrial stasis of blood in the left atrium.

Atrial arrythmia may be treated using several methods. Pharmacological treatment of atrial fibrillation, for example, is initially the preferred approach, first to maintain normal sinus rhythm, or secondly to decrease the ventricular response rate. While these medications may reduce the risk of thrombus collecting in the atrial appendages if the atrial fibrillation can be converted to sinus rhythm, this form of treatment is not always effective. Patients with

continued atrial fibrillation and only ventricular rate control continue to suffer from irregular heartbeats and from the effects of impaired hemodynamics due to the lack of normal sequential atrioventricular contractions, as well as continue to face a significant risk of thromboembolism.

Other forms of treatment include chemical cardioversion to normal sinus rhythm, electrical cardioversion, and RF catheter ablation of selected areas determined by mapping. In the more recent past, other surgical procedures have been developed for atrial fibrillation, including left atrial isolation, transvenous catheter or cryosurgical ablation of His bundle, and the Corridor procedure, which have effectively eliminated irregular ventricular rhythm. However, these procedures have for the most part failed to restore normal cardiac hemodynamics, or alleviate the patient's vulnerability to thromboembolism because the atria are allowed to continue to fibrillate. Accordingly, a more effective surgical treatment was required to cure medically refractory atrial fibrillation of the heart.

On the basis of electrophysiologic mapping of the atria and identification of macroreentrant circuits, a surgical approach was developed which effectively creates an electrical maze in the atrium (i.e., the MAZE procedure) and precludes the ability of the atria to fibrillate. Briefly, in the procedure commonly referred to as the MAZE III procedure, strategic atrial incisions are performed to prevent atrial reentry and allow sinus impulses to activate the entire atrial myocardium, thereby preserving atrial transport function postoperatively. Since atrial fibrillation is characterized by the presence of multiple macroreentrant circuits that are fleeting in nature and can occur anywhere in the atria, it is prudent to interrupt all of the potential pathways for atrial macroreentrant circuits. These circuits, incidentally, have been identified by intraoperative mapping both experimentally and clinically in patients.

Generally, this procedure includes the excision of both atrial appendages, and the electrical isolation of the